K000457

MAY - 9 2000

February 9, 2000

Pre-market Notification [510(k)] Summary

Submitter: RetinaLabs.com, Inc
1776 Peachtree Street Suite 200 North
Phone: (404) 815-5233
Fax: (404) 873-3582

Official Correspondent: Frank J. Tighe

Trade Name: RetinaLabs.com, Inc., Photodynamic Therapy Pak

Common Name: Convenience Pak for Infusion

Registration Number: 1063514

Class: Class 1

Class Name: We were unable to find the device listed in the classification regulations, 21 CFR Parts 862-892 [807.87 (c)].

Panel: Ophthalmic

Product Code: HMX

K000457

Device Description: The RetinaLabs.com, Inc. Photodynamic Therapy Pak is a bundled convenience pak of pre-sterile items including syringes, needles,tubing,dextrose solution, and a catheter etc.

Statement of indications for use. - Convenience pak for infusing photo-sensitive solutions during photo-dynamic therapy.

Substantial Equivalence Comparison

	RetinaLabs.com	Alcon Surgical Procedure Paks
Contents: Standard Syringes, Needles, Catheter, Tubing Sets etc.	X	X
Sterilization: Pre-sterile components, Gamma & ETO bundled in a convenience container.	X	X

Sterility

All included items are in individual pre-sterile packages and are purchased from OEMs including but not limited to Baxter, Becton Dickinson, Abbott Laboratories, Gelman Sciences, Johnson & Johnson, and Kendall.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2000

Frank Tighe
Retinalabs.com
1776 Peachtree Street
Suite 200 North
Atlanta, GA 30309

Re: K000457
Trade Name: Photo-dynamic Therapy Pak
Regulatory Class: I
Product Code: HMX
Regulation: 886.4350
Dated: February 9, 2000
Received: February 11, 2000

Dear Mr. Tighe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

In addition, we have determined that your device kit contains 5% Dextrose Solution, USP, which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

David M. Whipple
for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K 000457

RETINALABS .com

510(k) Number: N/A

Device Name: Photodynamic Therapy Pak

Indications For Use: Convenience pak for infusing photo-sensitive solutions during ophthalmic photo-dynamic therapy.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X___ (Per 21 CFR 8O1.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000457

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